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Award Number: W81XWH-05-2-0015

TITLE: Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption

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14. ABSTRACT
This project is evaluating a brief smoking cessation intervention for use in primary care settings. The Brief Counselor Assisted Program (BCAP) combines motivational interviewing, behavioral counseling and nicotine replacement therapy [NRT; nicotine patch and buproprion (Zyban)] with an emphasis on reducing alcohol consumption as a strategy for minimizing smoking cessation related weight gain. Participants are randomly assigned to BCAP or to a Self-Guided Program (SGP) where they receive NRT and a pamphlet discussing change strategies for tobacco cessation, minimizing weight gain, and how to plan for and deal with possible relapses. Participants in BCAP have two clinic appointments and two phone counseling sessions. Current smokers in either group at 3-month follow-up, blocked by original group assignment, are randomized to receive either no further counseling or to attend a clinic booster session focusing on dealing with their individual obstacles to change. All participants will be followed up for 12 months. As of December 19, 2007, a total of 259 participants had entered the study, 128 in the BCAP group and 131 in the SGP group. 3-month follow-up has been completed on 89.5% of the 228 participants due for that follow-up and increase as interviews are completed with more participants. Our focus continues to be on recruitment and performance of the study.

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Annual Report Award Number W81XWH-05-2-0015

Introduction

This report summarizes progress made on Award Number W81XWH-05-2-0015 for the third project year, from December 27, 2006 through December 26, 2007. The project, "Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption," involves developing and testing a brief smoking cessation intervention for use in primary care settings. The intervention is intended to help participants stop smoking cigarettes and stay quit by use of motivational interviewing, behavioral counseling and nicotine replacement therapy with an emphasis on reducing alcohol consumption as a strategy for minimizing weight gain related to smoking cessation. Participants are randomly assigned to one of two groups: a Brief Counselor Assisted Program (BCAP), or a Self-Guided Program (SGP), with the nicotine patch and buproprion (Zyban) available to all participants. Participants in the BCAP attend two 30-minute clinic appointments and have two counseling sessions by phone over a period of 8-10 weeks, where tobacco cessation skills are integrated with weight and alcohol reduction strategies. Participants in the SGP receive, in addition to the medication, a pamphlet discussing the most effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up, blocked by original group assignment, are randomized either to receive no further counseling or to attend one clinic booster session focusing on dealing with their individual obstacles to change. All participants will be followed up for 12 months. The study addresses three research questions: (1) Does an alcohol reduction strategy designed to minimize weight gain produce higher smoking cessation rates than a control treatment? (2) Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse? (3) Does providing a stepped care intervention (booster) for participants who initially are unsuccessful at stopping improve long-term tobacco cessation rates?

Body

During the previous project year (Year 2), we completed development of the extensive treatment protocol and data forms for the project, gained approval of final materials from the Wilford Hall Medical Center IRB and the Nova Southeastern University IRB, and began the formal randomized controlled trial that is presently underway. The original Statement of Work required objectives to be itemized for each investigator and consultant and by necessity, therefore, includes considerable redundancy. To make this report better organized and easier to follow, we will first discuss progress made toward objectives shared among the investigators. Following that, individual Statement of Work accomplishments will be presented.

The major project priority for the Year 3 budget period has been recruitment of participants into the project. It had originally been planned that there would be an ample flow of smokers referred to the project from the Kelly Family Medicine Clinic (KFMC); however, as the project was initiated and began full scale operation it became apparent that this procedure was plagued by two problems. The first problem was that primary care staff already feel overwhelmed with their duties and adding additional screening and referral responsibilities while fine on paper and agreeable to the staff, only worked rarely in the real life setting. To be sure, this was not a reflection of staff malevolence or lack of care but rather reflected the reality of too much to do in too little time. The second issue had to do with staff turnover at the KFMC, which required continual training and monitoring of new staff. In mid-December of 2006, right before the end of the Year 2 budget period, we put several measures into effect to facilitate recruitment. These included having research assistants on site at the KFMC to offer information to and arrange screenings for clients; the placement of posters at the KFMC, Wilford Hall Medical Center and at strategic locations at Lackland Air Force Base, and periodic base wide emails about the study. These procedures have worked well for increasing recruitment. As of December 19, 2007, we had screened 1,020 individuals for the study, of whom 259 had entered the study and another 8 were scheduled to enter the study but had not yet completed their first appointment. The most common reason for ineligibility was insufficient alcohol consumption, accounting for 458 screen outs. We have found the high incidence of low reported alcohol consumption to be puzzling, as it is somewhat inconsistent with survey data. Looked at differently, however, slightly over 25% of the smokers evaluated for the study were eligible and agreed to participate. Our originally proposed sample size was 682, which incorporated blocking on gender and expectations of attrition of 20% at follow-up. However, the basis for separate gender analyses evaluations was weak (females tend to be more concerned about weight gain) and our statistical consultants have assured us that gender effects can still be readily analyzed as a covariate. As explained in the original proposal, the minimum sample size required to achieve adequate statistical power is 284, which allowing for a 20% follow-up attrition would yield a minimum required sample of 356 (356-72 = 284). Clearly this is within reach, as we currently have 258 enrolled participants and 8 scheduled to enter the study. However, according to the timeline projected in the original proposal, recruitment would have been completed at the start of the Year 3 budget period. As a result of the need to revise recruiting procedures described above, however, as well as as the somewhat lower than expected recruitment rate (presumably affected by many factors including prospective participants' knowledge that they may be deployed in the near future), it became clear that we would need to recruit for a longer period in order to enroll the required sample size. Anticipating this development and it's corollary implication that we would eventually need to seek an unfunded extension of the grant period, we took measures to economize wherever possible in order to be able to operate the project for an extended period within the original budget. As will be seen in budget documents and a revised Statement of Work to be submitted separately from this report, we will be requesting an unfunded additional year for the grant. If, based on that submission, we are approved for a revised Year 4 budget and an unfunded Year 5

extension, we expect to successfully complete all project procedures and to develop several publications and presentations based on the findings. In order to complete the project with a sufficient sample size, our recruitment target in the budget revisions for which approval will be separately requested will be 356 participants, for reasons described above, but we would hope to exceed that number and end up with more than 400 participants. The reason we want to recruit as many participants as possible during the remainder of the project is because this will increase the statistical power of secondary analyses, an important part of the project. During budget Year 4, in addition to continuing to recruit, treat and follow-up participants, a major focus will be on data entry and cleaning, preliminary statistical analyses, and preparation of presentations and publications of findings. During budget Year 5, the unfunded extension year to be requested, follow-up will be completed, full project data analyses will be completed, and presentation and publication of findings will be the major priority. These aspects are reflected in a revised Statement of Work to include an additional project year, and a requested revised budget to include an additional project year funded by carry forward of unexpended funds. In terms of timeline, we propose to continue recruitment until the end of September 2008. Although this would extend completion of 12-month follow-up through the third quarter of budget Year 5, all analytic procedures would be in place by that time and the statistical analyses would only require updating with the final data.

The project experienced some staff changes in budget Year 3 of the grant. In February, the Project Coordinator, Dr. Lisa Alvarez, left her position. After extensive consultation among the investigators, it was decided to promote Ms. Antoinette Brundige, at that time the Project Interviewer and a staff member from the start of the project, to be the new Project Coordinator. During the remainder of the budget year Ms. Brundige has proved herself to be extremely capable and an excellent supervisor and contributor to the project. Ms. Crystal Mendoza was hired to replace Ms. Brundige as Project Inteviewer, and this also has worked out extremely well with Ms. Mendoza rapidly achieving competence at all required project duties. During budget Year 3, as in the previous budget periods, we found it necessary to make more investigator site visits to Wilford Hall Medical Center than had originally been anticipated because many issues (e.g., participant solicitation strategies, data storage and transmission) were better handled with focused all staff meetings than could be achieved by telephone or email. Now that recruitments, treatment and follow-up are running smoothly, the frequency of visits is planned to be reduced, but some visits are still essential to work out project details and to continue staff cohesiveness.

The following completes the body of this report in a more standard format, reporting achievement of benchmarks in the Statement of Work.

Mark B. Sobell, Ph.D.

1. Hire project team members: Completed Year 1.
2. Finalize formal protocol, manuals: Completed, see above.

3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
4. Monitor compliance with, and integrity of, the treatment protocols: Ongoing.
5. Monitor the quality control of all the data collection required for the project: Ongoing.
6. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective once sufficient data have been collected to begin statistical analyses.
7. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: This objective will become effective once sufficient data have been collected to begin statistical analyses.
8. Generate the final manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.
9. Disseminate results and materials produced by the study: This objective will become effective after the performance of the formal project has been completed.

Linda C. Sobell, Ph.D.
1. Hire project team members: Completed Year 1.
2. Finalize formal protocol, manuals: Completed, see above.
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
4. Train personnel in project intervention: Completed.
5. Monitor compliance with, and integrity of, the treatment protocols: Ongoing.
6. Monitor the quality control of all the data collection required for the project: Ongoing.
7. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective once sufficient data have been collected to begin statistical analyses.
8. Oversee the conduct of project follow-up: Ongoing.
9. Generate the final manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.
10. Disseminate results and materials produced by the study: This objective will become effective after the performance of the formal project has been completed.

Col. Alan Peterson, Ph.D.
1. Review/coordinate IRB approvals: Completed.
2. Hire project team members: Completed Year 1.
3. Secure office space for WHMC grant staff: Completed.
4. Finalize formal protocol, manuals: Completed, see above.
5. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
6. Coordinate the training of phone counselors this project: Completed.
7. Provide weekly clinical supervision of phone counselors and monitor compliance with, and integrity of, the treatment protocols: Ongoing.
8. Monitor the quality control of all the data collection required for the project: Ongoing.

9. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: This objective will become effective once sufficient data have been collected to begin statistical analyses.
10. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: This objective will become effective once sufficient data have been collected to begin statistical analyses.
11. Supervise WHMC military and grant staff in assessment and intervention procedures: Ongoing.
12. Generate scientific conference presentations of study preliminary results: This objective will become effective after the performance of the formal project has been completed.
13. Review/coordinate IRB amendments and annual reports: Ongoing.
14. Generate the final manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.
15. Disseminate results and materials produced by the study: This objective will become effective after the performance of the formal project has been completed.

Maj. Christopher Hunter, Ph.D.

1. Revise intervention manuals: Completed, see above.
2. Assist in finalization of assessment instruments: Completed, see above.
3. Assist in training of military and grant staff to work in the primary care setting: Completed.
4. Generate manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.

Maj. Christine Hunter, Ph.D.

1. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed, see above.
2. Assist in training of telephone counselors: Completed.
3. Assist in weekly supervision of phone counselors: Participates in weekly conference calls, but has separated from the military.
4. Generate manuscripts of study results: See above

Lt.Col. Ann Hryshko-Mullen, Ph.D.

Dr. Hryshko-Mullen is one of three Wilford Hall Medical Center staff members who have been added to the research team after the Permanent Change of Station (PCS) of Capt. Jeffrey Goodie, Ph.D. in August 2005. Dr. Mullen is the Chief of the Clinical Health Psychology Service at Wilford Hall.
1. Maintained Wilford Hall office space for all grant staff personnel: Ongoing.
2. Coordinated with Lackland AFB Tobacco Cessation Program to limit any overlap or conflict with proposed study and ongoing Tobacco Cessation programs: Ongoing.

3. Manuals: Completed, see above.
4. Assist in training staff to work in primary care setting: Completed.
5. Generate manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.

Maj William Isler, Ph.D.

Dr. Isler has had a permanent change of station and is no longer associated with this project.

Capt Steve Schmidt, Ph.D.

Dr. Schmidt has had a permanent change of station and is no longer associated with this project.

Keith Haddock, Ph.D.

1. Provide consultation on development of database for study and computerize data entry: Completed, see above.
2. Oversee entry of project data, plan for statistical analyses: Ongoing.
3. Conduct statistical analyses, consult on interpretation of findings: This objective will become effective when the project database is sufficiently large to allow statistical analyses.
4. Generate manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.

Carlos Poston, Ph.D.

1. Provide consultation on development of database for study and computerize data entry: Completed, see above.
2. Oversee entry of project data, plan for statistical analyses: Ongoing.
3. Conduct statistical analyses, consult on interpretation of findings: This objective will become effective when the project database is sufficiently large to allow statistical analyses.
4. Generate manuscripts of study results: This objective will become effective after the performance of the formal project has been completed.

Timothy Baker, Ph.D.

1. Provide consultation on smoking cessation treatment protocol and development of database: Completed, see above.
2. Help monitor integrity of study implementation: Ongoing.
3. Provide consultation on data analysis strategies: This objective will become effective when the project database is sufficiently large to allow statistical analyses.

4. Provide consultation on interpretation of results: This objective will become effective when the project database is sufficiently large to allow statistical analyses.

Key Research Accomplishments.

- Continued recruitment of participants into the project, adding 182 participants this budget year.
- Continued performance of treatment protocol with participants.
- Continued conduct of collection of follow-up data on participants.
- Continued required IRB approvals for project.
- Began data entry into project database.

Reportable Outcomes

As recruitment is continuing for the project, reportable outcomes are still few. In the previous project year a poster describing the project was presented at the Department of Defense Military Health Research Forum, San Juan, Puerto Rico, May 2006. During Year 3 a poster describing the project was presented at the annual meeting of the American Psychological Association in August, 2007. This poster is included as an appendix:

Sobell, M. B., Peterson, A. L., Sobell, L. C., Hunter, C. L., Hunter, C. M., Alvarez, L., Brundige, A., & Goodie, J. Alcohol Reduction to Facilitate Smoking Cessation and Prevent Relapse. Poster presented at the Annual Meeting of the American Psychological Association, San Francisco, CA, August, 2007.

Conclusions

The project is ongoing and early objectives have been met in terms of developing materials and gaining IRB approval and establishing steady throughput of participants into the project. Recruitment is now proceeding at a desired rate, but we will be requesting in separate documentation to add an additional unfunded year to the project supported by carry forward funding. This will allow us to achieve a sample size for the statistical analyses that will have sufficient statistical power. Although the evaluation of outcomes awaits the collection of sufficient data for preliminary analyses, progress to date has demonstrated the feasibility of the treatment protocol.

References

None at this time.

Appendices

Poster presented at the annual meeting of the American Psychological Association, San Francisco, CA, August 2007.

Alcohol Reduction to Facilitate Smoking Cessation and Prevent Relapse

Mark B. Sobell[1], PhD, Linda Carter Sobell[1], PhD, Alan L. Peterson[2,5], PhD, Christopher L. Hunter[3], PhD, Christine M. Hunter[4], PhD, Lisa Alvarez[5], PhD, Antoinette Brundige[5], MA, Jeffrey L. Goodie[6], Ph.D.

1. Nova Southeastern University, 2. University of Texas Health Science Center at San Antonio, 3. National Naval Medical Center, 4. National Institute of Diabetes & Digestive & Kidney Diseases, 5. Wilford Hall Medical Center, 6. Uniformed Services University of the Health Sciences

Introduction

- Concern about weight gain is a well established barrier to smoking cessation.
- In the military, concern about weight gain after quitting is of heightened concern because excessive weight can result in being unfit for service.
- This study targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.
- A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.
- Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.
- It is expected that participants who reduce their alcohol use will have a lessened risk of relapse to smoking.

Research Questions

1. Does weight gain minimization using an alcohol reduction strategy produce higher smoking cessation rates than a control treatment?
2. Does participation in a tobacco cessation program that includes an alcohol reduction component reduce the risk of relapse?
3. Does a booster session for participants who initially are unsuccessful at stopping improve long-term smoking cessation rates?

Design

- The first two research questions are being evaluated using a two-group randomized design.
- Eligible participants, blocked by gender, are randomized to groups.
- For those who have not stopped smoking at the 3-month follow-up, half, blocked by initial treatment condition, are randomly assigned to receive a booster session.
- Follow-up is for one year post-treatment.

Treatment Conditions

1. **Brief Counselor Assisted Program:** Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.

2. **Self-Guided Program:** Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. Bupropion SR and NRT provided.

- The **Booster** session focuses on overcoming barriers to smoking cessation, and development of new quit and relapse prevention plans.

Participants

- Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) are the primary source of participants.
- All participants are eligible military medical beneficiaries.

Inclusion Criteria

1. At least 21 years of age
2. Smoke an average of 5+ cigarettes a day for the past year
3. Consume 4 or more standard drinks per week on average
4. Concerned about gaining weight after stopping smoking
5. Planning to stay in the local area for one year.

Exclusion Criteria

1. Pregnant, breastfeeding, or planning to become pregnant.
2. Health conditions including history of seizure, head injury, eating disorder, liver disease and/or hypertension that excludes use of cessation medications.
3. Having taken prescription or nonprescription weight-loss medication within 6 months prior to screening
4. Medical contraindication (case-by-case basis).
5. Temporarily assigned to the base to attend a military training program.
6. No recent or current major depression
7. Diagnosed with alcohol abuse or dependence

Current Status

- As of mid-July, 2007, more than 200 participants had been enrolled in the study. Follow-up is ongoing.

Relevance

- While concerns about weight gain affect most individuals attempting to stop smoking, concerns in the military are heightened because of the potential impact of weight gain, increased abdominal circumference, or failure to meet the overall fitness standards.

Better Health
One Step at a Time!

*This study is supported by a grant from the Peer Review Medical Research Program (DAMD17-00-1-0296)